Section 5 510(k) Summary of Safety and Effectiveness

5. 510(k) Summary

AUG 28 2012

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	BASF VENTURE CAPITAL AMERICA INC.
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FACSIMILE:	(914) 785-2166
CONTACT PERSON:	Nadi Ergenc, Ph.D.
DATE PREPARED:	July 30, 2012
TRADE NAME:	Enluxtra™ Humifiber™ Wound Dressing
COMMON NAME:	Wound Dressing
CLASSIFICATION NAME:	Dressing, Wound, Drug
DEVICE CLASSIFICATION:	Unclassified (Pre-Amendment)
PRODUCT CODE	FRO
PREDICATE DEVICES:	Enluxtra™ Humifiber ™ Wound Dressing, Class 1, 510k Exempt, Product Code NAC PolyFIT+ Absorbing Dressings (K092351), Unclassified SoloSite Conformable Dressing (K981150), Unclassified

Substantially Equivalent To:

The Enluxtra™ Humifiber™ Wound Dressings are substantially equivalent in intended use, principles of operation and technological characteristics to the legally marketed Enluxtra™ Humifiber ™ Wound Dressing, Class 1, 510k Exempt , Product Code NAC, and PolyFIT+ Absorbing Dressings (K092351), Unclassified (Pre-Amendment), Product Code FRO, and SoloSite Conformable Dressing (K981150), Unclassified, Product Code MGQ.

Description of the Device Subject to Premarket Notification:

Enluxtra™ Humifiber™ Wound Dressings are soft non-woven fiber based wound care devices that are designed for use on exuding wounds and as effective barriers to reduce microbial penetration through the dressing.

Enluxtra™ Humifiber™ Wound Dressings are made of synthetic polymers, consisting of a hydrophilic gelling fiber core enclosed between a wound contact fiber layer and backing film. When the dressing is in contact with breached skin/wound and absorbs wound exudate, the polymer fibers form a gel. The backing film supports the gel and allows for simple one-piece removal of the dressing from the wound.

The film prevents fluid strike-through and serves as a microbial barrier to reduce microbial penetration through the dressing.

The Enluxtra™ Humifiber™ Wound Dressings are provided as sterile, single use, disposable devices and will be available in a variety of sizes.

Indication for Use:

Enluxtra Humifiber™ Wound Dressings are intended as an effective barrier to reduce microbial penetration through the dressing. The Enluxtra Humifiber™ Wound Dressings are for use under healthcare professional's orders for the management of exuding wounds, partial and full thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds.

Technical Characteristics:

The Enluxtra™ Humifiber™ Wound Dressings have similar physical and technical characteristics to the predicate devices. The Enluxtra™ Humifiber™ Wound Dressings and the predicates have the same design, are made of the same or similar non-resorbable synthetic polymers, are for single use and are sterilized by radiation.

Performance Data:

All necessary verification and validation tests have been performed for the Enluxtra™ Humifiber™ Wound Dressings to assure substantial equivalence to the predicate devices:

- Absorbency,
- Microbial barrier/strike through,
- Biocompatibility, including the following tests:

#	Test	Results
1	Cytotoxiciity – ISO Agar Diffusion	Non-Toxic/ Passed
2	Intracutaneous (Intradermal) Reactivity	Non-irritant/ Passed
3	Maximization Test for Delayed-Type Hypersensitivity	Negative for evidence of sensitization
4	Acute Systemic Toxicity	Non-Toxic/ Passed
5	Hemolysis Test – Extraction and Direct contact Methods	Non-Hemolytic

- Bacterial Mutagenicity (not mutagenic)

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Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Enluxtra™ Humifiber™ Wound Dressings are determined to be substantially equivalent to existing legally marketed devices.

All performance characteristics of the Enluxtra™ Humifiber™ Wound Dressings are the same or similar as the predicates.

The Enluxtra™ Humifiber™ Wound Dressings raised no new safety concerns relative to biocompatibility. Testing performed on the Enluxtra™ Humifiber™ Wound Dressing showed that it was non-toxic, non-irritant, negative for evidence of sensitization, non-hemolytic and non-mutagenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 28 2012

BASF Venture Capital America, Incorporated
% Nadi Ergenc, Ph.D.
100 Campus Drive
Floram Park, New Jersey 07932

Re: K122297
Trade/Device Name: Enluxtra™ Humifiber™ Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 31, 2012
Received: July 31, 2012

Dear Dr. Ergenc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K122297**

Device Name: **Enluxtra Humifiber™ Wound Dressings**

Indications for Use:

Enluxtra Humifiber™ Wound Dressings are intended as an effective barrier to reduce microbial penetration through the dressing. The Enluxtra Humifiber™ Wound Dressings are for use under healthcare professional's orders for the management of exuding wounds, partial and full thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds.

OR

Prescription Use _X_ Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122297